

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

Janice Lightner, Executrix of the Estate)	
of Ralph Liscio, Deceased and Janice)	
Lightner in her own right,)	
)	
Plaintiffs,)	
v.)	COMPLAINT AND DEMAND
)	FOR JURY TRIAL
Takeda Pharmaceuticals America, Inc.;)	
Takeda Pharmaceuticals, U.S.A., Inc.)	
(formerly known as Takeda Pharmaceuticals)	
North America, Inc.); Takeda Pharmaceutical)	
Company Limited)	
)	
Defendants.)	

COMPLAINT

Plaintiff, Janice Lightner, Executrix of the Estate of Ralph Liscio, deceased and Janice Lightner in her own right ("Plaintiff") is an individual who resides at 33 Kingwood Drive, Little Falls, Passaic County, New Jersey, and by and through the undersigned attorneys, hereby brings this cause of action against Defendants Takeda Pharmaceuticals America, Inc. ("Takeda America"), and Takeda Pharmaceuticals, U.S.A. Inc., f/k/a Takeda Pharmaceuticals North America, Inc. ("Takeda U.S.A.") and Takeda Pharmaceutical company Limited ("TPC") (collectively "Takeda" or "Defendants") and as for her Complaint alleges, upon information and belief as follows:

INTRODUCTION

1. This is a personal injury and Wrongful Death action brought for injuries caused to Plaintiff, Janice Lightner, and to decedent, Ralph Liscio, as a result of decedent ingesting Defendants' drug Actos (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with type II diabetes. Decedent was prescribed and took Actos upon direction of his physician. Decedent developed bladder cancer and died on June 10, 2012.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides. Venue is proper pursuant to 28 U.S.C. § 1391 in that defendants are corporations subject to personal jurisdiction in the judicial district in which this action is commenced.

PLAINTIFF

3. Plaintiff, Janice Lightner is a natural person and her father, Ralph Lisico, used the prescription Actos as prescribed and directed by his physician.
4. Decedent was personally injured and died as a result of his use of Actos, and his Estate and Heirs therefore seek damages under the New Jersey Survival Act and the New Jersey Wrongful Death act.

DEFENDANTS

5. Takeda America is a Delaware Corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.
6. Takeda America is a wholly owned subsidiary of Takeda U.S.A.
7. Takeda America has regularly transacted and conducted business within the State of New Jersey.
8. Takeda America has derived substantial revenue from goods and products, including Actos, used in the State of New Jersey.
9. Takeda America expected or should have expected its acts and omissions to have consequences within the State of New Jersey, and derived substantial revenue from interstate commerce.
10. Takeda U.S.A. is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.
11. Takeda U.S.A. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, (TPC") which has its principal place of business in Osaka, Japan.
12. Takeda U.S.A. has regularly transacted and conducted business within the State of New Jersey.
13. Takeda U.S.A. has derived substantial revenue from goods and products, including Actos, used in the State of New Jersey.
14. Takeda U.S.A. expected or should have expected its acts to have consequences within the State of New Jersey, and derived substantial revenue from

interstate commerce.

15. Takeda Pharmaceutical Company Limited ("TPC") is the parent company of Takeda America and of Takeda U.S.A., and is a Japanese corporation with its principal place of business is Osaka, Japan.

16. TPC wholly owns, controls, manages, operates and directs Takeda America and Takeda U.S.A. in all matters relating to Actos and Actoplus (Pioglitazone).

17. TPC has regularly transacted and conducted business within the State of New Jersey.

18. TPC has derived substantial revenue from goods and products, including Actos and Actoplus, used within the State of New Jersey.

19. TPC expected or should have expected its acts and omissions to have consequences within the State of New Jersey, and derived substantial revenue from interstate commerce.

SUMMARY OF THE CASE

20. As a result of the defective nature of Actos, decedent, who was prescribed and who ingested this product, suffered and died from bladder cancer and related medical conditions.

21. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from decedent, his physicians, other consumers, and the medical community. Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer associated with Actos ingestion including but not limited to ingestion over 12 months.

22. As a result of Defendants' actions and inaction, and their defective product, decedent was injured due to his ingestion of Actos, which caused decedent's injuries and death. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

23. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos, for the treatment of type two diabetes mellitus.
24. Takeda America Research and Development Center, Inc. developed Actos in Princeton, New Jersey, while it was a wholly owned subsidiary of Takeda Pharmaceutical Company, Limited. Actos was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type II diabetes while Takeda America Research and Development Center, Inc. had its principal place of business in Princeton, New Jersey. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD"s). Actos marketing by defendants, or by its agents which it controlled, began in 1999.
25. Type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.
26. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat type II diabetes and should not be used to treat type I diabetes.
27. Actos is sold as a single ingredient product under the brand name Actos, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

28. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve (12) months, including decedent, have suffered from bladder cancer.
29. Defendants concealed and continue to conceal their knowledge regarding Actos causing bladder cancer from decedent, other consumers, and the medical community. Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos for more than twelve (12) months.
30. As a result of Defendants' actions and inactions and their defective product, decedent was injured due to his ingestion of Actos, which caused decedent various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.
31. Prior to Actos being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.
32. In 2005, the results of the PROactive (**PRO**spective PioglitAzone **Clinical Trial In MacroVascular Events**) three-year study were published. The PROactive study prospectively looked at the impact in total mortality and macrovascular morbidity using Actos. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitA zone Clinical Trial In Macro Vascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1289 (2005).
33. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving

Actos versus comparators. This information was not included in the published Dormandy paper.

34. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.
35. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use.
36. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos.
37. In 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. Pioglitazone is the active ingredient in Actos. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."
38. Piccinni, et al. supra analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System ("AERS")

between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. The study's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk."

39. On June 9, 2011, the European Medicines Agency ("EMA") announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review.
40. France's decision was based upon a retrospective cohort study of the Caisse Nationale De' Assurance Maladie in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).
41. On or about June 10, 2011, Germany joined France in suspending the use of Actos after Germany's Federal Institute for Drugs and Medical Devices ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.
42. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA recommended that physicians discontinue pioglitazone use in patients with active bladder cancer. The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

43. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposure to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.
44. On July 12, 2011, Takeda Pharmaceutical Company Limited issued a recall of Actos in France.
45. As the manufacturers of Actos, Defendants knew or should have known that Actos use for longer than 12 months was associated with bladder cancer. Defendants chose to promote Actos as a safe and effective treatment for type II diabetes.
46. Despite its knowledge of this dangerous side effect that can result from Actos use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.
47. Actos is one of Defendants' top selling drugs. Actos has had global sales of \$4.8 billion and it has accounted for 27% of Takeda's revenue. In 2008, Actos was the tenth best-selling medication in the United States.
48. Consumers, including decedent, who have used Actos for treatment of type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos therapy.

49. Defendants, through their affirmative misrepresentations and omissions, actively concealed from decedent and his physicians the true and significant risks associated with longterm Actos use.

50. As a result of Defendants' actions, decedent and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that decedent had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, misrepresentations and defective product. Decedent did not mis-use the drug. Decedent would not have used the drug if defendants had properly disclosed the risks.

51. As a direct and proximate result of ingesting Actos for more than twelve months, decedent has been permanently and severely injured; required medical care and treatment for which he and his Estate has incurred medical expenses; suffered severe mental and physical pain and suffered and sustained severe emotional distress; had economic loss and loss of enjoyment of life; all of which contributed to and caused his death.

52. Plaintiff lost services, support, society, advice, comfort, and companionship of her father, before and after decedent's death.

FEDERAL REQUIREMENTS

53. Defendants had an obligation to comply with federal law in the manufacture, design, and sale of Actos.

54. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*

55. With respect to the prescription drug Actos, the Defendants, failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to,

one or more of the following violations:

- a. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.
- b. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.
- c. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.
- d. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- e. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of

administration or application, in such manner and form as are necessary for the protection of users.

- f. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- g. The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.
- h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.
- i. The prescription drug Actos is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading

- j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed
- k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.
- l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.
- m. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.
- n. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.
- o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

- p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug Actos.
- q. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.
- r. The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.
- s. The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.
- t. The prescription drug Actos violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

- u. The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.
- v. The prescription drug Actos violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.
- w. The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.
- x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.
- y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.
- z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.
- aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and

submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

- bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.
- cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."
- dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.
- ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report

because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

gg. The Defendants violated 21 CFR § 314.70 by failing to change its label to strengthen its warning.

56. Defendants failed to meet their obligations set by the above and other statutes and regulations, which were intended for the benefit of individual consumers such as the decedent, and the Defendants are liable under New Jersey law.

COUNT ONE

PRODUCT DEFECT IN DESIGN **New Jersey Product Liability Act**

57. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

58. At all times herein mentioned, Defendants manufactured, designed, formulated, marketed, advertised, distributed, promoted and sold Actos, used by decedent.

59. The Defendants' Actos was in an unsafe, defective, and inherently and unreasonably dangerous condition when it left the control of defendants.

60. Defendants' Actos was defective in that at the time Actos left the control of Defendants, it could cause bladder cancer, and these risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

61. At all times herein mentioned, Defendants' Actos was in a defective condition and was unreasonably dangerous and Defendants knew, had reason to know, or should have known that said Actos was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.
62. The nature and magnitude of the risk of harm associated with the design and formulation of Defendants' Actos, including bladder cancer, is high in light of the intended and reasonably foreseeable use of Actos for type II diabetes.
63. It is highly unlikely that Actos users and their physicians would be aware of the risks associated with Defendants' Actos through either warnings, general knowledge or otherwise. Decedent and his physician were not aware of said risks.
64. The likelihood was high that the design or formulation would cause the serious harm of bladder cancer, in light of the intended and reasonably foreseeable use of Actos to for type II diabetes.
65. The design or formulation of Defendants' Actos is more dangerous than a reasonably prudent consumer, patient or physician would expect when used in the intended or reasonable foreseeable manner for type II diabetes. It was more dangerous than decedent expected.
66. The intended or actual utility of Defendants' Actos is not of such benefit to justify the risk of bladder cancer and even death.
67. There was both technical and economic feasibility, at the time the Defendants' Actos left Defendants' control, of decedent using an alternative that would not cause bladder cancer. There are and were safer alternative therapies available on the market to treat type II

diabetes, that effectively reduce blood sugar without the harmful side effects, such as bladder cancer, that can result from long-term Actos use.

68. By reason of the foregoing, the Defendants are liable under New Jersey law to the Plaintiff for the manufacturing, designing, formulating, marketing, advertising, distributing and sale of a product that is defective in design and formulation, which directly and proximately caused the injuries set forth above.

69. Plaintiff is entitled to punitive damages because Defendants' failure to warn was reckless and without regard for decedent's and the public's safety and welfare. Defendants misled the FDA, physicians and the public at large, including decedent by making false representations about the safety of Actos. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of Actos and pioglitazone.

70. At all times relevant hereto, Defendants by and through an officer, director, or managing agent, authorized sales representative, employee and/or other agent engaged in malicious, fraudulent and oppressive conduct towards decedent and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of decedent and the general public.

71. The acts and/or willful omissions of Defendants as set forth *supra*, were such knowing and willful failures to warn of adverse effects inherent in the use of Actos and pioglitazone hydrochloride, that they constituted malicious, willful, wanton and/or reckless conduct within the meaning of the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.2 *et seq.*

72. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensation damages as set forth above, and for punitive damages, and costs of suit.

COUNT TWO

**PRODUCT DEFECT DUE TO INADEQUATE
WARNING AND FAILURE TO WARN
New Jersey Product Liability Act**

73. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

74. Defendants had a duty to warn decedent and his physicians of the risks associated with the Defendants' Actos, namely, the risk of bladder cancer.

75. Defendants knew, or in the exercise or reasonable care should have known about, the risk of bladder cancer.

76. Defendants failed to provide warnings or instructions that a manufacturer and seller, exercising reasonable care, would have provided concerning the risk of bladder cancer, in light of the likelihood that their product would cause bladder cancer, from which decedent suffered.

77. Defendants' Actos is defective due to inadequate post-marketing warning or instruction.

78. Defendants had a post-sale continuing duty to warn decedent and his physician.

79. Defendants' Actos at all times material hereto did not contain a warning or instruction regarding the risk of bladder cancer for normal healthy individuals.

80. The risk of bladder cancer is not an open and obvious risk or a risk that is a matter

of common knowledge in regards to Actos, nor is it a risk reasonably known by physicians.

Decedent and his physician did not know the risk. Decedent would not have used the drug if defendants had properly disclosed the risks.

81. By reason of the foregoing, the Defendants are liable under New Jersey law to the Plaintiff, for the inadequate warning or instruction or failure to warn, which directly and proximately caused the injuries set forth above.
82. Plaintiff is entitled to punitive damages because Defendants' failure to warn was reckless and without regard for decedent's and the public's safety and welfare. Defendants misled the FDA, physicians and the public at large, including decedent, by making false representations about the safety of Actos. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent adverse health effects associated with the use of Actos.
83. At all times relevant hereto, Defendants by and through an officer, director, or managing agent, authorized sales representative, employee and/or other agent engaged in malicious, fraudulent and oppressive conduct towards decedent and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.
84. The acts and/or willful omissions of Defendants as set forth *supra*, were such knowing and willful failures to warn of adverse effects inherent in the use of Actos and pioglitazone hydrochloride, that they constituted malicious, willful, wanton and/or reckless conduct within the meaning of the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.2 *et seq.*

85. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensation damages as set forth above, and for punitive damages, and costs of suit.

COUNT THREE

BREACH OF EXPRESS WARRANTIES

N.J.S.A. 12A:2-313, et seq.

86. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

87. Defendants expressly warranted that Actos was safe for its intended use and as otherwise described in this complaint. Actos did not conform to these express representations, including, but limited to, the representation that it was well accepted in patient and animal studies, that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects like bladder cancer, that it would improve health, maintain health, and potentially prolong life, rather than potentially decrease health and reduce life expectancy.

88. The express warranties represented by the Defendants were a part of the basis for decedent's use of Actos and decedent and his physician relied on these warranties in deciding to use Actos.

89. At the time of the making of the express warranties, the Defendants had knowledge of the unreasonably dangerous nature of Actos when ingested for the purpose for which the Actos and pioglitazone hydrochloride was intended and yet still warranted Actos to be in all respects safe, effective and proper for such purpose.

90. Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among other things bladder cancer and degrading decedent's health.
91. By reason of the foregoing, the defendants are liable to the plaintiff for not conforming to its express warranties, which directly and proximately caused the injuries set forth above.
92. By reason of the foregoing, Plaintiff demands judgment against each Defendant individually, jointly and severally for compensatory damages as set forth above, and for punitive damages, and costs of suit.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

- a. Awarding compensatory damages to the Plaintiff;
- b. Awarding punitive damages to the Plaintiff;
- c. Awarding pre-judgment and post-judgment interest to the Plaintiff;
- d. Awarding the costs and the expenses of this litigation to the Plaintiff;
- e. Awarding reasonable attorneys' fees to the Plaintiff as provided by law; and
- f. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

LOCKS LAW FIRM LLC

BY: 

James J. Pettit, Esquire
Attorney for the Plaintiffs

Date:

6/10/13